NOV - 2 2000

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: 001249

Submitter: Consolidated Technologies of Wisconsin, Incorporated
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Austin, TX 78744-1832
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Contact: Rusty Sewell

Preparation date: 12 September 2000

Product name (trade & common):
Proprietary: QUALITROL DHP IMMUNOASSAY CONTROL, Levels 1, 2 and 3
Common: Not Applicable
Also Sold As: CONFORMANCE® MCC™-Ligand Control, Levels 1, 2 and 3
Common: Not Applicable

Classification name:
Class I , Product code: JJY
21 CFR 862:1660 : Multi-Analyte Controls, All Kinds (Assayed and Unassayed)

Predicate device:
QUALITROL DHP IMMUNOASSAY CONTROL, Levels 1, 2 and 3.
Consolidated Technologies, Incorporated
K-972080

Device description:
QUALITROL DHP IMMUNOASSAY CONTROL (or CONFORMANCE MCC-Ligand Control) is designed to monitor the performance of test procedures that analyze immunochemistries and therapeutic drugs as listed in the package insert.
19 new components are to be added to the previously approved device and one (1) previously claimed component is to be removed. An additional 19 components considered endogenous will be listed in the assay sheet as non-assayed.

Intended use:
QUALITROL DHP IMMUNOASSAY CONTROL (or CONFORMANCE MCC-Ligand Control) is a liquid human serum based assayed quality control material intended to monitor the performance of serum immunoassay test procedures that analyze immunochemistries and therapeutic drugs as listed in the package insert. .

Labeling:
QUALITROL Vial labels see Exhibit I
QUALITROL Secondary Container label, see Exhibit II
QUALITROL Package Insert, see Exhibit III
CONFORMANCE Vial labels see Exhibit IV
CONFORMANCE Secondary Container label, see Exhibit V
CONFORMANCE Package Insert, see Exhibit VI

Comparative analysis:
The table below provides a summary of the technological characteristics between QUALITROL DHP IMMUNOASSAY CONTROL (or CONFORMANCE MCC-Ligand Control) and the predicate device.

Device Characteristic	Proposed Device QUALITROL DHP IMMUNOASSAY CONTROL	Predicate Device QUALITROL DHP IMMUNOASSAY CONTROL
Intended use	Assayed quality control serum for monitoring performance of serum immunoassay and therapeutic drug test procedures.	Assayed quality control serum for monitoring performance of serum immunoassay and therapeutic drug test procedures
Matrix	Human Serum	Human Serum
Form	Liquid, Frozen	Liquid, Frozen
Analytes	76 analytes of clinical significance that may be found in serum. **Added Components**: 11-Desoxycortisol 17-α-Hydroxyprogesterone Aldosterone Amiodarone Amitryptiline Androsternedione Caffeine Chloramphenicol Desipramine DHEA-Sulfate Estriol-Free Ethosuximide Flecainide Human Growth Hormone Ibuprofen Imipramine Lidocaine Lithium Salicylate **Deleted Components** Digitoxin **Endogenous Components** BUN Calcium Chloride Creatinine Estriol Estrogen Iron Magnesium Netilmicin Potassium Sodium Uric Acid Thyroglobulin IgA, IgG, IgM, IgE 25-Hydroxy Vitamin D Fructosamine	37 analytes of clinical significance that may be found in serum
Storage	2-8°C	2-8°C
Stability	Until expiration date noted on vial label.	Until expiration date noted on vial label

Conclusions:
The information provided in the pre-market notification demonstrates that QUALITROL DHP IMMUNOASSAY CONTROL (or CONFORMANCE MCC-Ligand Control) is substantially equivalent to the predicate device, for which there is FDA clearance. This equivalence was demonstrated through comparison of intended uses and physical properties to a commercially available device. The information supplied in the pre-market notification provides reasonable assurance that QUALITROL DHP IMMUNOASSAY CONTROL is safe and effective for the stated intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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Mr. Rusty Sewell
Product Development Engineer
Consolidated Technologies of Wisconsin, Incorporated
2170 Woodward Street
Austin, Texas 78744-1832

Re: K001249
Trade Name: Qualitrol DHP Immunoassay Control, Levels 1, 2 and 3
Regulatory Class: I
Product Code: JJY
Dated: September 12, 2000
Received: September 12, 2000

Dear Mr. Rusty Sewell:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS OF USE STATEMENT

510(k) number (if known): K001249

Device name:

QUALITROL DHP IMMUNOASSAY CONTROL, Levels 1, 2 and 3
CONFORMANCE® MCC™ Ligand, Levels 1, 2 and 3

Indications for use:

QUALITROL DHP IMMUNOASSAY CONTROL, Levels 1, 2 and 3, (or CONFORMANCE® MCC™ Ligand, Levels 1, 2 and 3) is a liquid human serum based assayed quality control material intended to monitor the performance of clinical immunoassay test procedures that analyze immunochemistries and theraputic drugs as listed in this package insert.

Peter E Nadin

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K001249